NOV - 5 2009

510(k) Summary

ArthroCare® Corporation
Titan™ Ti Suture Anchor

General Information

Submitter Name/Address:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-3523
Establishment Registration Number:	2951580
Contact Person:	Valerie Defiesta-Ng Director, Regulatory Affairs
Date Prepared:	July 13, 2009

Device Description

Trade Name:	Titan Ti Suture Suture Anchor
Generic/Common Name:	Screw, Fixation, Bone; Fastener, Fixation, Nondegradable, Soft
Tissue	
Classification Name:	Smooth or Threaded Metallic Bone Fixation Fastener (21 CFR 888.3040)
Device Classification:	Class II, 21 CFR 888.3040 Product Code MBI and HWC

Predicate Devices

Arthrex Corkscrew FT Suture Anchor	K050358 cleared 04/15/05)
Arthrex Corkscrew FT Suture Anchor	K061665 (cleared 07/25/06)
Arthrex Corkscrew FT III Suture Anchor	K062679 (cleared 09/27/06)
Arthrex Corkscrew, Corkscrew FT, Bio-Corkscrew, and Bio Corkscrew FT Suture Anchor(s)	K061863 (cleared 10/19/06)

Product Description

The Titan Ti Suture Anchor is a fully-threaded, self-tapping, titanium corkscrew shape anchor available in 5.5mm and 6.5mm diameter sizes. The suture anchor comes preconfigured with MagnumWire® sutures and is mounted on a disposable delivery driver. The device is supplied sterile and is available with or without needles.

Intended Uses/Indications for Use

The Titan Ti Suture Suture Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, hip, knee, hand/wrist and elbow in the following procedures:

- Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tendodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction;
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament/Tendon Repair, Bunionectomy;
- Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Illiotibial Band Tenodosis;
- Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction;
- Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis repair;
- Hip: Capsular Repair, Acetabular Labral Repair

Substantial Equivalence

In establishing substantial equivalence to the predicate devices, ArthroCare compared the indications for use, dimensional specifications, and performance specifications of the subject device and the predicate device. Additionally, performance testing has been completed to demonstrate the substantial equivalence of the Titan Ti Suture Anchor to the predicate device. The performance testing and device comparison demonstrate that the subject devices are substantially equivalent to the predicate devices, and is safe and effective for its intended use.

Summary of Safety and Effectiveness

The Titan Ti Suture Anchor, as described in this premarket notification 510(k), is substantially equivalent to the predicate devices. The differences in performance specifications, and labeling are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

ArthroCare Corporation
c/o Ms. Valerie Defiesta-Ng
Director, Regulatory Affairs
680 Vaqueros Avenue
Sunnyvale, California 94085-3523

NOV - 5 2009

Re: K092133
Trade/Device Name: Titan™ Ti Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI
Dated: October 20, 2009
Received: October 21, 2009

Dear Ms. Defiesta-Ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

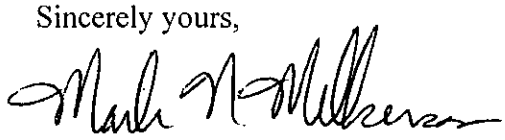
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Device Name Titan™ Ti Suture Anchor

510(k) Number: K092133

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use ____

(Per 21 CFR 801.109)

for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092133